



UNITED STATES PATENT AND TRADEMARK OFFICE

A

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/807,555 | 03/23/2004 | Paul Keane | P-4461/2 RI | 3418 |

7590 04/06/2005
David W Highet Esq
Becton Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ 07417

EXAMINER

ZEC, FILIP

ART UNIT PAPER NUMBER

3744

DATE MAILED: 04/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/807,555

Applicant(s)

KEANE ET AL.

Examiner

Filip Zec

Art Unit

3744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25-37 is/are allowed.
- 6) ☒ Claim(s) 38-42 and 46-53 is/are rejected.
- 7) ☒ Claim(s) 43-45 and 54-57 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 41 and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claims 41 and 52 recite the limitation "the second annular ring" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,196,998 to Jansen et al., in view of U.S. Patent 6,632,199 to Tucker et al. Jansen discloses applicant's basic inventive concept, a tip cap (26, FIG. 5) designed for a syringe (10, FIG. 4), the tip cap comprising a housing comprising a bottom portion (74, FIG. 5) having an annular skirt (82, FIG. 5) extending there from and an annular ring (56, FIG. 4) located within the skirt, the annular ring having an interior surface (66, FIG. 4) and an exterior surface (see FIG. 4) and at

Art Unit: 3744

least two deformable vertical strips (84, FIG. 4), capable of engaging and providing securement to a threaded (52, FIG. 8) luer connection (col 2, lines 55-68), substantially as claimed with the exception of having the at least two vertical strips on the exterior surface of said annular ring.

Tucker shows a tip cap having the at least two vertical strips (66, FIG. 4) on the exterior surface (64, FIG. 4) of an annular ring to be old in the drug delivery and syringe art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made from the teaching of Tucker to modify the system of Jansen, by having the at least two vertical strips on the outside surface of the annular ring instead of the inside surface of the annular skirt in order to provide stability and structural integrity (col 3, lines 27-29).

6. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,196,998 to Jansen et al., in view of U.S. Patent 6,632,199 to Tucker et al., as applied to claim 38 above, and further in view of U.S. Patent 6,027,482 to Imbert. Jansen in view of Tucker discloses applicant's basic inventive concept, a tip cap designed for a syringe, substantially as claimed with the exception of having a vent integral to the bottom portion of the tip cap housing. Imbert shows a vent (69, FIG. 4) integral to the bottom portion (56, FIG. 4) of the tip cap housing to be old in the drug delivery and syringe art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made from the teaching of Imbert to modify the system of Jansen in view of Tucker, by adding a vent integral to the bottom portion of the tip cap housing in order to control gas flow to and from the syringe minimizing the occurrence of vacuum when the cap is removed from the tip (col 4, lines 43-48).

7. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,196,998 to Jansen et al., in view of U.S. Patent 6,632,199 to Tucker et al., as applied to claim

Art Unit: 3744

38 above, and further in view of U.S. Patent 6,206,861 to Mayer. Jansen in view of Tucker discloses applicant's basic inventive concept, a tip cap designed for a syringe, substantially as claimed with the exception of having an interior surface of the annular ring comprising one or more planar portions. Mayer shows an interior surface (88a, FIG. 7) of an annular ring (84a, FIG. 7) comprising one or more planar portions (94a, FIG. 7) to be old in the drug delivery and syringe art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made from the teaching of Mayer to modify the system of Jansen in view of Tucker, by adding one or more planar portions to the interior surface of the annular ring in order to prevent bowing of the ring (col 18, lines 22-25).

8. Claims 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,196,998 to Jansen et al., in view of U.S. Patent 4,667,837 to Vitello et al. Jansen discloses applicant's basic inventive concept, a tip cap (26, FIG. 5) designed for a syringe (10, FIG. 4) having a barrel (12, FIG. 4), a syringe tip (22, FIG. 4) and a luer connection (44, FIG. 4) at a distal end of the barrel, the tip cap comprising a housing comprising a bottom portion (74) having an annular skirt (82) extending there from and an annular ring (56, FIG. 4) located within the skirt, said skirt extends approximately over the syringe such that the luer connection is contained within the interior of the housing (see FIG. 5), wherein upon engagement of the tip cap with the luer connection, the end of the skirt opposite the bottom portion surrounds a portion of the barrel, substantially as claimed with the exception of having the inner diameter of the skirt at the end of the skirt opposite the bottom portion greater than the outer diameter of the syringe barrel. Vitello shows the inner diameter of the skirt (11, FIG. 1) at the end of the skirt opposite the bottom portion greater than the outer diameter of the syringe barrel (15, FIG. 1) to be old in

Art Unit: 3744

the drug delivery and syringe art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made from the teaching of Vitello to modify the system of Jansen, by having the inner diameter of the skirt at the end of the skirt opposite the bottom portion greater than the outer diameter of the syringe barrel in order to provide a tighter seal and prevent accidental movement of the tip once it is engaged with the cap.

9. Claims 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,196,998 to Jansen et al., in view of U.S. Patent 4,667,837 to Vitello et al., as applied to claim 47 above, and further in view of U.S. Patent 6,632,199 to Tucker et al. Jansen in view of Vitello discloses applicant's basic inventive concept, a tip cap designed for a syringe having a barrel, a syringe tip and a luer connection at a distal end of the barrel, and at least two deformable vertical strips (Jansen: 84, FIG. 4), capable of engaging and providing securement to a threaded (52, FIG. 8) luer connection (col 2, lines 55-68), substantially as claimed with the exception of having the at least two vertical strips on the exterior surface of said annular ring. Tucker shows a tip cap having the at least two vertical strips (66, FIG. 4) on the exterior surface (64, FIG. 4) of an annular ring to be old in the drug delivery and syringe art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made from the teaching of Tucker to modify the system of Jansen in view of Vitello, by having the at least two vertical strips on the outside surface of the annular ring instead of the inside surface of the annular skirt in order to provide stability and structural integrity (col 3, lines 27-29).

10. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,196,998 to Jansen et al., in view of U.S. Patent 4,667,837 to Vitello et al., as applied to claim 47 above, and further in view of U.S. Patent 6,027,482 to Imbert. Jansen in view of Vitello

Art Unit: 3744

discloses applicant's basic inventive concept, a tip cap designed for a syringe having a barrel, a syringe tip and a luer connection at a distal end of the barrel, substantially as claimed with the exception of having a vent integral to the bottom portion of the tip cap housing. Imbert shows a vent (69, FIG. 4) integral to the bottom portion (56, FIG. 4) of the tip cap housing to be old in the drug delivery and syringe art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made from the teaching of Imbert to modify the system of Jansen in view of Vitello, by adding a vent integral to the bottom portion of the tip cap housing in order to control gas flow to and from the syringe minimizing the occurrence of vacuum when the cap is removed from the tip (col 4, lines 43-48).

Allowable Subject Matter

11. Claims 25-37 are allowed.
12. Claims 43-45 and 54-57 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent 6,394,983 to Mayoral, Joaquin et al. teaches a cap and luer connector for a fluid transfer device.

Art Unit: 3744

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Filip Zec whose telephone number is (571) 272-4815. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Denise Esquivel can be reached on (571) 272-4808. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Filip Zec
Examiner
Art Unit 3744


CHERYL TYLER
SUPERVISORY PATENT EXAMINER

FZ